

Attorney Docket No. J&J5092US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Georgios Stamatias et al. Confirmation No.: 2589
Application No.: 10/735,188 Group No.: 3768
Filed: December 12, 2003 Examiner: Jacqueline Cheng
For: METHOD OF ASSESSING SKIN

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Commissioner for Patents
P.O. Box 1450
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APPEAL BRIEF

Sir:

Further to the Notice of Appeal received by the USPTO on November 22, 2010, applicant hereby submits an Appeal Brief with the fee set forth in section 41.20(b)(2) herewith which is due on January 22, 2011 (Saturday).

The Commissioner is hereby authorized to charge any additional fees which may be required in connection with the filing of this communication, or credit any overpayment, to Account No. 10-0750.

CERTIFICATE OF EFS SUBMISSION (37 C.F.R. § 1.8(a)(1)(C))

I hereby certify that on January 24, 2011, that this correspondence is being submitted to the Patent and Trademark Office via the Office Electronic Filing System in accordance with § 1.6(a)(4).

/Margaret Turner/
Signature

Margaret Turner, Patent Paralegal
Type or print name of person certifying

I. Real Party In Interest

The real party in interest is JOHNSON & JOHNSON CONSUMER COMPANIES, INC., the assignee of record which is a subsidiary of Johnson & Johnson.

II. Related Appeals and Interferences

US application 10/986,941 has a currently pending appeal relating to the present pending patent application.

III. Status of Claims

Claims 11-20 are pending in the application. Claims 1-10 have been cancelled. This appeal is taken from the Examiner's final rejection mailed September 29, 2010, of claims 11-20. Claims 11-20 are being appealed.

IV. Status of Amendments

No amendments to the claims have been made in response to the Final Office Action mailed September 29, 2010.

V. Summary of Claimed Subject Matter

The present invention as defined in Claim 11 relates to a method of determining the effect of a treatment to the skin of a subject. The method includes (i) exposing a first area of skin to a first exposure radiation to induce said area of skin to emit a first fluorescent emission, wherein said first exposure radiation comprises primarily of wavelengths of from about 290 nm to about 300 nm and wherein said first area of skin was exposed to said treatment; (ii) measuring the intensity of said first fluorescent emission having a wavelength of from about 320 nm to about 350 nm; (iii) exposing said first area of skin to a second exposure radiation to induce said area of skin to emit a second fluorescent emission, wherein said second exposure radiation comprises primarily of wavelengths of from about 330 nm to about 420 nm; (iv) measuring the

intensity of said second fluorescent emission having a wavelength of from about 380 nm to about 470 nm; (v) calculating a ratio of said intensity measured in step (ii) to said intensity measured in step (iv); (vi) repeating steps (i) to (v) for a second area of skin, wherein said second area of skin was not exposed to said treatment; and (vii) comparing said ratio for said first area of skin to said ratio for said second area of skin; and (viii) determining and reporting the effect of the skin treatment based on said compared ratios.

Appellants have discovered a marker that strongly correlates with skin aging, based on the ratio of the fluorescence intensity due to tryptophan moieties (centered at 295 nm excitation, Steps (i) and (ii), above) to the fluorescence intensity assigned to collagen and elastin cross-links (centered at 390 nm excitation, Steps (iii) and (iv), above). This marker (calculated in Step (v), above) normalized the tryptophan band and was found to decrease with aging, and photoaging was found to accelerate the rate of the decrease. This normalization cancels the effects of pigmentation, and enables one to determine the relative health of the skin being assessed (see specification at page 14, line 16, through page 15, line 1).

Claim 11 is the independent claim pending in the application. Antecedent support for each element of claim 1 set forth below is noted in parenthesis following each claim element.

11. A method of determining the effect of a treatment to the skin of a subject, said method comprising the steps of:

- (i) exposing a first area of skin to a first exposure radiation to induce said area of skin to emit a first fluorescent emission, wherein said first exposure radiation comprises primarily of wavelengths of from about 290 nm to about 300 nm and wherein said first area of skin was exposed to said treatment (page 3 lines 20 through 26);

- (ii) measuring the intensity of said first fluorescent emission having a wavelength of from about 320 nm to about 350 nm (page 3 lines 26 through 28);
- (iii) exposing said first area of skin to a second exposure radiation to induce said area of skin to emit a second fluorescent emission, wherein said second exposure radiation comprises primarily of wavelengths of from about 330 nm to about 420 nm (page 3 lines 28 through 32);
- (iv) measuring the intensity of said second fluorescent emission having a wavelength of from about 380 nm to about 470 nm (page 3 line 32 through page 4, line 1);
- (v) calculating a ratio of said intensity measured in step (ii) to said intensity measured in step (iv) (page 4 lines 1 through 3);
- (vi) repeating steps (i) to (v) for a second area of skin, wherein said second area of skin was not exposed to said treatment (page 4 lines 22 through 24); and
- (vii) comparing said ratio for said first area of skin to said ratio for said second area of skin (page 4 lines 24 through 26); and
- (viii) determining and reporting the effect of the skin treatment based on said compared ratios (page 4 lines 5 through 7).

VI. Grounds of Rejection to be Reviewed on Appeal

Whether claims 11-20 stand properly rejected under 35 USC 103(a) as being unpatentable over Tregagnier (US 2002/0016534 A1) in view of Leffell (US 4,894,547).

VII. Argument

Claim Rejections – 35 USC § 103

Are claims 11-20 unpatentable under 35 USC 103(a) over Tregagnier (US 2002/0016534 A1) in view of Leffell (US 4,894,547)?

The Examiner's position has been that Trepagnier teaches exciting within the claimed wavelengths, measuring fluorescence within the claimed wavelengths, calculating relative peak ratios, and comparing the ratios to standards or surrounding skin, but does not disclose the particulars of how to perform the method for measuring treatment related change. The Examiner relied on Leffell, claiming that the reference teaches monitoring skin for improvements over time. Appellants respectfully disagree.

With respect to the Trepagnier reference, throughout the document the focus is on measuring blood glucose levels. Measurements can be taken for tryptophan, collagen, or other species to capture transient changes that relate to blood glucose levels. While combinations of wavelengths and various species may be measured, in no way does the reference teach or suggest the specific multiple wavelength measurements, generation of ratios, or comparison of ratios for treated versus untreated skin of the present invention. While the Examiner has pointed to various paragraphs in the reference, Appellants fail to see where these steps are specifically taught or suggested. Appellants respectfully submit that the Examiner is being overly broad in interpreting "calculating relative peak ratios". The reference certainly does not teach what peaks are to be compared to generate the ratios. Regardless, the reference could not be any clearer that the method is for measuring blood glucose or analyte levels.

Leffell teaches measurements for demonstrating effects from ultraviolet light exposure, which the Examiner seems to equate to a "treatment". The term "treatment" in the present invention relates to application of compositions that contain, for example

(and as demonstrated in the example of the specification), retinol to reduce or eliminate wrinkles. Nowhere in the reference does the Leffell patent define a treatment as a skin care composition containing active ingredients for wrinkle reduction. Furthermore, Leffell teaches away from the present invention as Leffell is directed to measuring skin pigmentation, while Appellants' method cancels the effects of skin pigmentation. Therefore, Appellants are assessing fluorescence and associated tryptophan levels, which are associated with cell proliferation and therefore relate to the health of the skin. Further, Leffell does not teach or suggest the specific multiple wavelength measurements, generation of ratios, or comparison of ratios for treated versus untreated skin of the present invention. Therefore, the combination of references does not render the present invention obvious.

In view of the above, Appellants respectfully submit that the prior art fails to anticipate and/or render obvious the claimed invention as recited in claims 11-20. Appellants ask the Board to carefully consider the arguments above and permit the claims to proceed to allowance.

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VIII. Claims Appendix

11. A method of determining the effect of a treatment to the skin of a subject, said method comprising the steps of:

- (i) exposing a first area of skin to a first exposure radiation to induce said area of skin to emit a first fluorescent emission, wherein said first exposure radiation comprises primarily of wavelengths of from about 290 nm to about 300 nm and wherein said first area of skin was exposed to said treatment;
- (ii) measuring the intensity of said first fluorescent emission having a wavelength of from about 320 nm to about 350 nm;
- (iii) exposing said first area of skin to a second exposure radiation to induce said area of skin to emit a second fluorescent emission, wherein said second exposure radiation comprises primarily of wavelengths of from about 330 nm to about 420 nm;
- (iv) measuring the intensity of said second fluorescent emission having a wavelength of from about 380 nm to about 470 nm;
- (v) calculating a ratio of said intensity measured in step (ii) to said intensity measured in step (iv);
- (vi) repeating steps (i) to (v) for a second area of skin, wherein said second area of skin was not exposed to said treatment; and
- (vii) comparing said ratio for said first area of skin to said ratio for said second area of skin; and
- (viii) determining and reporting the effect of the skin treatment based on said compared ratios.

12. A method of claim 11, wherein said first exposure radiation comprises primarily of wavelengths of about 295 nm.

13. A method of claim 12, wherein said step (ii) comprises measuring the intensity of said first fluorescent emission having a wavelength of about 340 nm.

14. A method of claim 11, wherein said second exposure radiation comprises primarily of wavelengths of from about 390 to about 410 nm.
15. A method of claim 12, wherein said second exposure radiation comprises primarily of wavelengths of from about 390 nm to about 410 nm.
16. A method of claim 13, wherein said second exposure radiation comprises primarily of wavelengths of from about 390 nm to about 410 nm.
17. A method of claim 14, wherein said step (iv) comprises measuring the intensity of said second fluorescent emission having a wavelength of about 440 nm.
18. A method of claim 15, wherein said step (iv) comprises measuring the intensity of said second fluorescent emission having a wavelength of about 440 nm.
19. A method of claim 16, wherein said step (iv) comprises measuring the intensity of said second fluorescent emission having a wavelength of about 440 nm.
20. A method of claim 11, wherein said first area of skin and said second area of skin are the same area of skin and wherein the calculation of the ratio for said second area of skin occurs prior to said treatment.

IX. Evidence Appendix

None.

X. Related Proceedings Appendix

None.